

## **Remarks**

### **I. Status of the Application and Claims**

As originally filed, the present application had a total of 16 claims. All of the original claims were cancelled and were replaced with claims 17-29 in a response filed by Applicant on July 26, 2004. Applicant has submitted new claims 30 and 31 in the present response. Therefore, upon entry of the present amendments, the claims pending in the application will be claims 17-31.

### **II. The Amendments**

Claim 18 has been amended extensively so that it is now differentiated from claim 17. Specifically, claim 18 now uses the transitional phrase “comprising” rather than “consisting essentially of.” Based upon the Office Action issued on May 6, 2004, Applicant believes that this language is probably acceptable to the Examiner.

Claims 20 and 26 were amended in accordance with the suggestion made by the Examiner in a previous Office Action. They no longer refer to a “unit dose form” or to a “therapeutically effective” amount of peptide. The “unit dose” requirement has been incorporated into claim 21 and claim 27. In addition, new claims 30 and 31 are based upon claims 20 and 26, but have been amended so that they recite specific diseases or conditions for which a “therapeutically effective amount” of peptide is being used. These claims, as well as the amendments to claims 20 and 26, were made for the purpose of overcoming the rejection under item 10 on page 4 of the present Office Action.

Claims 23 and 29 were amended to indicate that peptides are indicated for use in “reducing oxidation-related damage in a patient suffering from” stroke, heart attack or spinal injury. Similarly, an amendment was introduced to indicate that the compositions may be indicated for administration to a patient undergoing surgery “to reduce cellular injury resulting from oxidative stress.” These amendments were made for the purpose of overcoming the rejection under item 9 of the Office Action appearing on pages 3 and 4.

None of the amendments made herein add new matter to the application, and their entry is therefore respectfully requested.

### **III. Objection to Specification**

On page 2 of the Office Action, the Examiner objects to the specification because, although Applicant cross-referenced another application relied upon for priority, this did not appear as the first sentence in the application. Applicant has amended the specification to correct this error, and therefore respectfully submits that the Examiner's objection has been obviated.

### **IV. Comments Regarding Sequence Listing**

On page 2 of the Office Action, the Examiner indicates that the Sequence Listing rules have not been fully complied with because the specification fails to include sequence identification numbers, particularly with respect to the legend for Figure 1 appearing on page 4 of the specification.

In response, Applicant respectfully submits that this defect was corrected in a document entitled "Amendment to Comply with Sequence Listing Rules" that was submitted on February 17, 2004. A copy of this document, along with a copy of the date-stamped postcard indicating receipt by the Patent and Trademark Office on February 17, 2004, is enclosed herewith as Exhibit A.

A review of the PAIR page of the Patent Office indicates that it did receive the Amendment filed on February 17, but Applicant was only able to find two pages of the document that was submitted available for viewing on the Internet. To the extent that certain pages may have been misplaced, this defect can be corrected using the enclosed document.

**V. Comments Regarding Claims 17 and 18**

On page 3 of the Office Action, the Examiner discusses claims 17 and 18 and appears to suggest that they are of identical scope. Applicant does not fully agree with this assessment, but has, nevertheless, amended claim 18 to better differentiate it from claim 17.

**VI. Objection to Claims 28 and 29**

In item 8 on page 3 of the Office Action, the Examiner objects to claims 28 and 29 under 37 C.F.R. § 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only and cannot depend from any other multiple dependent claim.

Applicant has reviewed claims 28 and 29 but believes that they already comply with the requirements of patent law. Claim 28 refers to “either claim 26 or claim 27” and therefore meets the requirement of referring to claims in the alternative. Claim 28 is a multiple dependent claim, but it depends from singly dependent claims. Claim 29 refers back to a multiple dependent claim, *i.e.*, claim 28, but is not itself multiple dependent. Thus, Applicant could not find any instance where there is a multiple dependent claim that is depending from another claim that is also multiple dependent. Applicant therefore respectfully requests that the Examiner’s objection be withdrawn.

**The Rejections****I. Rejection of Claims Under 35 U.S.C. § 112, First Paragraph**

On pages 3 and 4 of the Office Action, the Examiner rejects claims 23 and 29 based upon the allegation that they fail to comply with the written description requirement of patentability. The Examiner argues:

No proper antecedent basis nor conception in context with that described within the specification at the time of filing Applicant’s invention exists for the broader conception of any type of undefined treatment “wherein said pharmaceutical composition *is indicated for use in the treatment of stroke*,

heart attack, spinal injury, or *for administration to a patient before surgery.*” In contrast, page 4 of the specification contemplates “*for reducing oxidation-related damage in a patient suffering from a stroke...*,” or “*administered ... prior to a patient undergoing surgery to reduce cellular injury resulting from oxidative stress;*” thereby, constituting new matter.

In response, Applicant has amended both claim 23 and 29 so that they now incorporate the language that the Examiner cites as being present in the specification. In light of these amendments, Applicant respectfully submits that the Examiner’s rejection has been overcome.

## **II. Rejection of Claims Under 35 U.S.C. § 112, Second Paragraph**

On page 4 of the Office Action, the Examiner rejects claims 20, 22, 26 and 28-29 under 35 U.S.C. § 112, second paragraph, as being indefinite and incomplete. The Examiner argues:

Similar to that previously made of record, the recitation of “in unit dosage form comprising a *therapeutically effective amount*” is indefinite, because the metes and bounds are not defined because no disease state, dosage, etc. is recited in the claims, in order to determine what “*therapeutically effective amount*”/dosage is envisioned, etc.

In response, Applicant has amended claims 20 and 26 to adopt language previously suggested by the Examiner. Specifically, reference to a “unit dose form” and a “therapeutically effective amount” of peptide has been deleted from the claims. Claims 21 and 27 now require the presence of a unit dose form, but these also specify a particular amount of peptide, *i.e.*, 0.01-10 mg. Applicant has also used claims 20 and 26 to construct new claims 30 and 31, which are the similar but which recite specific diseases and conditions undergoing treatment. Thus, the argument that the claims are indefinite because a disease state is not indicated to determine what a “therapeutically effective amount” means has been obviated. In light of these amendments, Applicant believes that the Examiner’s rejection of claims under 35 U.S.C. § 112, second paragraph has been overcome.

### Conclusion

In light of the amendments and discussion above, Applicant submits that all of the Examiner's rejections have been overcome. It is therefore respectfully requested that these rejections be withdrawn and that the claims presently pending in the application be allowed.

If, in the opinion of the Examiner, a phone call may help to expedite the prosecution of this application, the Examiner is invited to call Applicant's undersigned attorney at (202) 419-7013.

Respectfully submitted,

FITCH, EVEN, TABIN & FLANNERY

By: Michael A. Sanzo

Michael A. Sanzo  
Reg. No. 36,912  
Attorney for Applicant

Date: December 20, 2004  
1801 K St., NW, Suite 401L  
Washington, DC 20006  
(202)419-7013

Attachment: Exhibit A – Amendment to Comply  
with Sequence Listing Rules filed  
February 17, 2004, with copy of  
date-stamped postcard.



**RECEIPT FROM USPTO FOR INDICATED ITEMS**

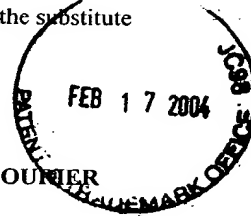
Appln. No.: 09/978,178  
Inventor(s): ROGERS, JACK  
Filed: OCTOBER 17, 2001  
Title: **PEPTIDES DERIVED FROM THE HUMAN AMYLOID  
PRECURSOR PROTEIN**

Attorney: M. Sanzo  
Date: February 17, 2004  
C/M # 7570/73272

**WHEN RECEIPT STAMP IS PLACED HEREON, THE USPTO ACKNOWLEDGES RECEIPT OF  
THE FOLLOWING DOCUMENTS:**

**OUR COVER LETTER ENCLOSING:**

1. Response to Restriction Requirement;
2. A copy of the Detailed Action - Sequence Rules;
3. Amendment to Comply with Sequence Listing Rules;
4. Paper copy of substitute Sequence Listing;
5. A 3.5 inch diskette containing a computer readable form of the substitute  
Sequence Listing; and
6. Return postcard.



**PLEASE DATE STAMP AND RETURN BY COUNTER**



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re patent application of:

Rogers, Jack

Appl. No.: 09/978,178

Filed: October 17, 2001, 2001

For: Peptides Derived from the Human Amyloid  
Precursor Protein

Group Art Unit: 1647

Examiner: R. Hayes

Atty. Dkt. 7570/73272

**Amendment to Comply with Sequence Listing Rules**

Commissioner of Patents  
U.S. Patent and Trademark Office  
2011 South Clark Place  
Customer Window  
Crystal Plaza Two, Lobby, Room 1B03  
Arlington, VA 22202

Sir:

In response to the Office Action dated January 21, 2004, Applicant is submitting the present Amendment to Comply with Sequence Listing Rules.

**Amendments to the Sequence Listing** are described on page 2 of this response and replacement pages are enclosed herewith.

**Amendments to the Specification** begin on page 3 of this response.

**Remarks** begin on page 4 of the present response.

**Amendments to the Sequence Listing**

Please delete the Sequence Listing presently pending in the application. Please enter the substitute Sequence Listing enclosed herewith in its place



**Amendments to the Specification**

Please amend the paragraph that appears on page 4 of the application, lines 31-34, to read as follows:

Figure 1: Figure 1 shows a portion of the APP protein (SEQ ID NO:8) that includes the RERMS domain (SEQ ID NO:9) and FOX-1 ~~domains~~ domain (SEQ ID NO:5). A2 (SEQ ID NO:10) and 827 (SEQ ID NO:6) are both peptides which encompass a portion of the RERMS sequence (SEQ ID NO:9). Also shown is the location of these peptides with respect to a KPI insertion site and a peptide designated as A $\beta$  (SEQ ID NO:11).

## **Remarks**

### **I. The Amendments**

The specification of the application was amended to add a new Sequence Listing that includes certain sequences that are shown in Figure 1. In addition, the legend for Figure 1 that appears on page 4 of the application was amended to include sequence identification numbers.

### **II. Submission of Computer Readable Form of Sequence Listing**

Enclosed herewith is a 3.5 inch computer diskette containing a copy of the enclosed Sequence Listing in ASCII text.

### **III. Statements to Comply with Sequence Listing Rules**

In compliance with 37 C.F.R. § 1.821(f), Applicant's undersigned attorney hereby states that the content of the paper and computer readable copies of the Sequence Listing submitted herewith are the same. In accordance with 37 C.F.R. § 1.821(g), Applicant's undersigned attorney hereby states that the Sequence Listing submitted herewith does not add new matter to the application.

## **Conclusion**

In light of the amendments and remarks above, Applicant submits that the Sequence Listing Rules have now been fully complied with. It is therefore respectfully submitted that this application is now in condition for substantive review.

If, in the opinion of the Examiner, a phone call may help to expedite this matter, the Examiner is invited to call Applicant's undersigned attorney at (202)419-7013.

Respectfully submitted,

FITCH, EVEN, TABIN & FLANNERY

By: \_\_\_\_\_

*Michael A. Sanzo*

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Reg. No. 36,912

Attorney for Applicant

Date: February 17, 2004  
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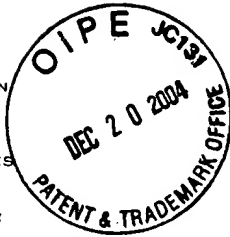
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December 20, 2004

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## TECHNICAL ADVISOR

JOHN M. BRONK, Ph.D.

\*ADMITTED TO D.C. BAR; D.C. PRACTICE OF  
ALL OTHERS LIMITED TO FEDERAL COURTS  
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Commissioner of Patents  
U.S. Patent and Trademark Office  
220 20<sup>th</sup> Street South  
Customer Window, MS AF  
Crystal Plaza Two, Lobby, Room 1B03  
Arlington, VA 22202

Re: Amendment and Response  
Appl. No.: 09/978,178  
Filed: October 17, 2001  
Title: **Peptides Derived from the Human  
Amyloid Precursor Protein**  
Inventor(s): Rogers, Jack  
Atty. Dkt.: 7570/73272

Dear Sir:

The following documents are being submitted herewith for appropriate action by the U.S. Patent and Trademark Office:

1. Amendment and Response Under 37 C.F.R. § 1.116 with Exhibit A;  
and
2. Return postcard.

As indicated below, Applicant does not believe that any fees are due for the filing of this response. However, the Director is hereby authorized to charge any fee deficiency with respect to this filing and any other fee required in connection with the present case, or credit any overpayment, to our Deposit Account No. 06-1135 under Order No. 7570/73272.

**CALCULATION OF ADDITIONAL FEES**

Applicant(s) have calculated additional fees as follows (Small Entity Status is claimed):

	No. After Amendment	No. Previously Paid for	No. Extra	Rate	Fee
Total Claims Fee	23	66=	0	\$ 25.00	0.00
Independent Claims Fee	2	3 =	0	\$ 100.00	0.00
Multiple Dependent Claims Fee (Previously Paid)	0	0	0	\$ 180.00	0.00
Total Additional Claims Fee					0.00
<b>TOTAL FEES DUE</b>					<b>0.00</b>

It is respectfully requested that the enclosed postcard be stamped with the date the enclosed documents are received by the PTO and that it be returned as soon as possible.

Very truly yours,

FITCH, EVEN, TABIN & FLANNERY



Michael A. Sanzo  
Reg. No. 36,912  
Attorney for Applicant

MAS:ct  
Enclosures

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